GE Consumer & Industrial

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May 14, 2004

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Application for Extension of Variance -- FDA Docket # 96V-0474

Dear Sir or Madam:

Please extend the above-captioned variance for an additional five years. A copy of the original variance is attached.

(1) **Variance Number And Expiration Date:** 96V-0474 -- Expires Oct. 13, 2003.

(2) **Basis for Extension Request:** There is no change in the product that was the subject of the original variance. GE still manufactures model CMH Ceramic Metal Halide lamps 70 watts or less, including the model CMH35, with the UV-absorbing material coating the quartz capsule that encases the arc tube. The following description of the product in the original variance is still correct:

> "It is not possible to break or puncture the outer quartz capsule without causing damage to the arc tube that would render the lamp inoperable resulting in no ultraviolet radiation being emitted. Therefore, the labeling, packaging and advertising provisions of 21 CFR 1040.30(e) are inappropriate and unnecessary."

(3) **Effect Of Extension On Radiation From The Product:** None -- product is protected against UV emission as described above.

(4) **Explanation Of Alternative Means Of Protection:** See response to item (2) above.

Thank you for your consideration of this request. Please contact me if you have any questions.

Cordially,

Lee L. Bishop

LLB/plt
Enclosure
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 13 1998

Ref: FDA Docket No. 96V-0474
Accession No. 96A0553-01

Mr. A.M. Zielinski
Lighting Environment
Health and Safety Department
General Electric Company
1975 Noble Road, Nela Park,
Cleveland, Ohio 44112

Dear Mr. Zielinski:

In accordance with 21 CFR 1010.4(c)(1), notice is given that the petition of General Electric Company, for an amendment to their variance, Number 96V-0474 from the lamp labeling, packaging, and advertising requirements of 21 CFR 1040.30(e) for high-intensity mercury vapor lamps is approved. These lamps are not self-extinguishing.

This variance, under the conditions stated below, will allow the introduction into commerce of all model CMH, Ceramic Metal Halide lamps 70 watts or less including and not limited to the model CMH35 as indicated in paragraph D below which are manufactured by General Electric Company.

A. Variance Number

96V-0474

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance amendment shall be terminated five years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for all the model CMH70 Ceramic Metal Halide (CMH) lamps 70 watts or less including and not limited to the CMH35. These small low powered lamps are designed for use in commercial display cases for illumination purposes.

E. Provisions From Which Variance is Granted

The variance is granted from all of the lamp labeling, packaging, and advertising provisions of 21 CFR 1040.30(e).

F. Conditions Under Which Variance is Granted

In lieu of the provisions referred to in Item E above, the following conditions shall apply to a;; the model CMH70 ceramic metal halide lamps 70 watts or less including and not limited to the model CMH 35, manufactured under this variance.

1. The products will not emit ultraviolet radiation levels of sufficient intensity or quality under any reasonable conditions of operation, maintenance, service, or product failure to be hazardous.

2. The products are produced in such a way that the provisions of the standard are inappropriate and unnecessary. Your documentation stated that the model CMH70 lamp 70 watts or less including and not limited to the model CMH35 uses an arc tube of design similar to that of a high pressure sodium lamp in combination with a mercury and metal halide dose. The arc tube is enclosed in a quartz capsule that has been doped with ultraviolet absorbing material so that the quartz capsule is no longer transparent to ultraviolet light. The small quartz capsule is designed to be just fractionally larger than the arc tube that it encloses. Further, your documentation stated it is not possible to break or puncture the outer quartz capsule without causing damage to the arc tube which would render lamp inoperable resulting in no ultraviolet radiation being emitted. Therefore, the labeling, packaging, and advertising provisions of the 21 CFR 1040.30(e) are inappropriate and unnecessary.

3. The current specification for the product will not be changed unless the request for a variance amendment is submitted to this office.

G. Basis for Approval of Variance

The Center for Devices and Radiological Health has determined, in accordance with 21 CFR 1010.4(a), that the labeling, packaging, and advertising provisions of the 21 CFR 1040.30(e) are not appropriate, and a suitable means for assuring radiation safety or protection are provided.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

"This product is in conformity with performance standards for high intensity mercury vapor lamps 21 CFR 1040.30, except with respect to those characteristics authorized by Variance Number 96V-0474 effective ...."

This variance amendment action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance amendment will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Also, under the authority of 21 CFR 1002.50, the Center for Devices and Radiological Health hereby approves your exemption from the abbreviated reporting requirements of 21 CFR 1002.12. The model CMH70 lamps 70 watts or less including and not limited to the model CMH35 lamps do not emit ultraviolet radiation of sufficient intensity or quality under any reasonable conditions of operation, maintenance, service, or product failure to be hazardous. The model CMH70 lamps 70 watts or less are produced in such a way the reporting requirements are inappropriate and unnecessary.

Sincerely yours,

Gladys Rodriguez

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health